

### **Remarks**

Claims 14, 23, 32, and 36-39 have been amended. Claims 17, 26, 34, and 40-46 have been cancelled. Claims 1-13, 16, and 20-22 were cancelled in the previous Response(s). New claims 47-49 have been added. Claims 14, 15, 18, 19, 23-25, 27-33, 35-39, and 47-49 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### **Amendment After Final Rejection**

Although the Examiner has discretion over entry of amendments submitted after final rejection, any amendment that will place the application either in condition for allowance or in better form for appeal may be entered. *See* MPEP 714.12. Any amendment after final rejection should require only a cursory review by the Examiner, such as an amendment cancelling claims, adopting Examiner suggestions, and/or removing issues for appeal. *See* MPEP 714.13 II.

Applicant respectfully requests entry of the amendments and remarks presented herein into the file for the above-identified application.

As discussed in further detail below, claims have been cancelled and amended in the instant Response. Dependent claims 40-42 and 46 have been cancelled. Dependent claims 17, 26, and 34 have been cancelled and the subject matter incorporated into independent claims 14, 23, and 32. An element (a combination) from independent claim 23 has been incorporated into independent claims 14 and 32. Claims 37-39 have been amended in accordance with suggestions of the Examiner. *See* rejection under 35 U.S.C. §112, second paragraph. Claims 43-45, reciting a method, have been cancelled and rewritten as new claims 47-49 in accordance with suggestions of the Examiner. *See* rejection under 35 U.S.C. §112, second paragraph.

Accordingly, the claim amendments made herein are acceptable for entry as, in accordance with the guidelines, they (the amendments) only cancel claims and adopt the suggestions of the Examiner.

Furthermore, all subject matter presented in the claims (as amended herein) has been previously presented. No new matter, which would require a further search by the Examiner, has been added.

Based upon all the above, it is clear that the amendments made herein require only a cursory review by the Examiner. Therefore, the instant Response places the application in condition for allowance or alternatively, in a better form for appeal, and should be entered.

#### Amendments to the Claims

No new matter has been added by the amendments (...a combination of...) to claims 14 and 32 made herein. This amendment has been made to clarify that the food/food bar comprises a combination of phosphatidyl serine and simple carbohydrates. In addition to the support found in claim 23, this subject matter is supported by the specification as originally filed, for example at paragraphs [0020]-[0022] of the published application, U.S. Patent Application Publication 2004/0120985 A1; hereinafter "published application."

No new matter has been added by the amendments (...wherein the carbohydrates are simple carbohydrates selected from the group consisting of glucose, fructose, sucrose, and combinations thereof.) to claims 14, 23, and 32 made herein. These claims have been amended to incorporate the subject matter of cancelled claims 17, 26, and 34. The amendments clarify that the carbohydrates contained in the food/food bar are simple carbohydrates, such as glucose, fructose, sucrose, and combinations thereof. In addition to the support found in the cancelled claims, this subject matter is supported by the specification as originally filed, for example at paragraphs [0020] and [0052] of the published application. Claim 36 was amended in light of the amendment to claim 32.

No new matter has been added by the amendments to claims 37-39 made herein. These

claims were amended to specify a particular simple carbohydrate, *i.e.* glucose, for inclusion in the food/food bar. This subject matter is supported by the specification as originally filed, for example at paragraph [0020] of the published application.

No new matter has been added by the addition of claim 47. This claim incorporates subject matter of cancelled claims 17, 26, or 34 and 43 and clarifies that a consumer can improve his/her cognitive function by consuming the recited food/food bar. In addition to the support found in the cancelled claims, this subject matter is also supported by the specification as originally filed, for example at paragraph [0053] of the published application and claim 3 as originally filed.

No new matter has been added by the addition of claims 48 and 49. These claims incorporate subject matter of cancelled claims 44 and 45 and clarify that the improvement in cognitive functional capacity can occur in the short term (claim 48) after consumption of the food/food bar or conversely in the long term (claim 49) after consumption of the food/food bar for a period of one to three weeks. In addition to the support found in the cancelled claims, this subject matter is supported by the specification as originally filed, for example at paragraphs [0025] and [0053] of the published application.

Rejections under 35 U.S.C. §112, second paragraph

Claims 37-42 and 46 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, regarding claims 40-42 and 46, the Examiner asserts that the term “greater” renders the claims indefinite, *i.e.* the term “greater” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant respectfully disagrees. One of ordinary skill in the art would be able to quantitatively compare numerical values in sets of data. However, although Applicant asserts one of ordinary skill would know how to ascertain the requisite degree of “greater” effects,

claims 40-42 and 46 have been cancelled in the interest of advancing prosecution.

Likewise, regarding claims 37-39, the Examiner asserts that the term “high” renders the claims indefinite, *i.e.* the term “high” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant respectfully disagrees. The term “glycemic index” is a well known term for expressing the amount of fluctuation in blood glucose levels in the body produced by consumption of a particular food. Furthermore, the ranges denoting foods of low, medium, and high glycemic index are known. *See* the paragraph bridging paragraphs 17-18 and Exhibit C of the previous Response filed on June 12, 2009. Thus, one of ordinary skill in the art would be able to identify carbohydrates having a high glycemic index. However, although Applicant asserts one of ordinary skill in the art would be able to ascertain the scope of the claims, claims 37-39 have been amended to remove the term “high” in the interest of advancing prosecution. The Examiner asserts that the phrases “short term” and “long term” (claims 44 and 45 respectively) render the claims indefinite because the metes and bounds are not defined.

Applicant respectfully disagrees. Claims 44 and 45 have been cancelled. New claims 48 and 49 correspond to these cancelled claims. Although Applicant disagrees with the Examiner’s assessment of the phrases, new claims 48 and 49 have been written to clarify the phrases; claim 48 to clarify that the improvement in cognitive functional capacity can occur in the short term after consumption of the food/food bar and claim 49 to clarify that the improvement in cognitive functional capacity can occur in the long term after consumption of the food/food bar for a period of one to three weeks. In addition to the support found in the cancelled claims, this subject matter is supported by the specification as originally filed, for example at paragraphs [0025] and [0053] of the published application.

In light of all the foregoing, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §103(a)

Claims 14, 15, 17-19, and 23-46 were rejected under 35 U.S.C. §103(a), as being unpatentable over Buchholz et al. (U.S. Patent 6,514,973 B1; hereinafter “Buchholz”) in view of Lang et al. (U.S. Patent Application Publication 2003/0161861 A1; hereinafter “Lang”). Claims 17, 26, 34, and 40-46 have been cancelled. The subject matter of cancelled claims 17, 26, and 34 has been incorporated into claims 14, 23, and 32. New claims 47-49 have been added. These new claims incorporate the subject matter of cancelled claims 43-45. The Examiner refers to claim 1 throughout this section (rejection under 103). Since claim 1 has previously been cancelled, Applicant interprets the statements made by the Examiner regarding claim 1 as applicable to claim 14.

For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches. Thus, presentation of individual descriptions (of the references) is not and should not be interpreted as an attempt “to argue the references separately.”

The teachings of Buchholz and Lang are as applied in the previous Responses filed on June 12, 2009 and December 19, 2008 and are reiterated herein for the convenience of the Examiner.

Buchholz

Buchholz discloses compositions for the treatment and prevention of transmethylation disorders, particularly for the treatment of neurological and pathopsychological diseases. *See* column 1, lines 6-8. The compositions contain three active ingredients; component A: one or more phosphatidyl serines, component B: one or more methyl transporters, and component C: one or more compounds selected from methyl and methylene donors, provided that the phosphatidyl serines and compounds with methyl transporting properties do not form part of component C. *See* abstract and column 1, line 61 to column 2, line 7. These compositions are

useful for reducing elevated levels of homocysteine found in transmethylation disorders. *See* column 1, line 37 to column 2, line 12.

Buchholz discloses, as background, a previous study demonstrating the long-term benefits of phosphatidyl serine supplementation. In this study, it was documented that oral supplementation with 200-300mg of phosphatidyl serine per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate, especially in aging people and in patients with certain neurological and pathopsychological conditions. *See* column 2, lines 22-27. However, in the actual composition disclosed by Buchholz, phosphatidyl serine was added only in an amount of 50mg. *See* Example 1.

Buchholz does not teach the role of carbohydrates in improving cognitive function of the brain. Further, Buchholz does not discuss any connection or relationship between phosphatidyl serine and glucose intake in the brain, other than to mention that it has been assumed that phosphatidyl serine is able to stimulate glucose metabolism in the brain. *See* column 2, lines 32-37.

The compositions disclosed by Buchholz are suitable as foods or food supplements and are prepared by combining the active ingredients, components A-C, with edible “nutritional substances”, including carbohydrates. Thus, Buchholz adds carbohydrates only to make the phosphatidyl serine more palatable for consumption, and therefore, considers the “nutritional substances”, such as carbohydrates, to be inactive ingredients. *See* column 5, lines 40-49 and column 6, lines 9-12.

### Lang

Lang discloses the use of a cereal product such as a biscuit or cracker having a slowly digestible starch content relative to the total starch content higher than about 12 wt %, preferably higher than about 20 wt %, to improve cognitive performances, in particular memory retention,

attention, concentration, vigilance and/or mental well-being in people, and particularly in a child and an adolescent. *See* abstract.

In the background material, Lang discusses conflicting experimental results regarding the role of glucose in cognitive functions, some studies show glucose improves these functions, and others show glucose has no role in these processes. *See* paragraphs [0015] and [0016]. In actual results, Lang shows that the regulation of the glycemic index alone was insufficient to increase cognitive performances and demonstrates that certain cereal products significantly improve cognitive performance, by virtue of the choice of appropriate proportions between slowly digestible starch and the total starch present in the product. *See* paragraph [0017]. Lang does not disclose or suggest the use of phosphatidyl serine in the biscuit composition.

In experimental Example 1, Lang compares learning and locomotive activity in two groups of rats, one of which consumes Lang's biscuits and the other ready-to-eat cereals. The rats which consumed biscuits exhibited learning results which were significantly superior to those of the rats which consumed ready-to-eat cereals. Additionally, in locomotive activity, the rats which consumed a biscuit-based breakfast were calm, whereas the rats which consumed a breakfast based on ready-to-eat cereals were more active and showed signs of distress (more passages in the central compartment, this indicating higher distress, since the behavior of crossing a room along the diagonal rather than along the walls is unusual in rats). Lang concludes that the bioavailability of starch makes it possible to explain the differences in results in these experiments. As such, Lang discloses improving cognitive performance by consuming a food product which combines a certain proportion of slowly digestible starch with respect to the total starch content.

#### Instant Invention

Generally, the present invention provides a food/food bar for increasing/improving cognitive functional capacity, particularly a food for increasing memory, concentration, and attentiveness in the consumer of the food. *See* abstract; paragraph [0012] of the published

application; and claims 3 and 12 as originally filed. This food, preferably a bar of chocolate, has a phosphatidyl serine content ranging from 100-300mg and a relatively high carbohydrate content. *See* abstract. The carbohydrates are simple carbohydrates, such as glucose, fructose, sucrose, and/or combinations thereof. A preferred food/food bar, as currently claimed, includes a combination of a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of simple carbohydrates. *See* abstract; paragraphs [0020]; [0022]; and [0052]; and Figure 2A of the published application. In one embodiment, the food/food bar contains a minimum of 40 wt% to about 57 wt% of simple carbohydrates and a minimum of 1 wt% to 1.4 wt% of lecithin extract containing phosphatidyl serine. *See* paragraph [0022] of the published application.

By specifically combining the intake of simple carbohydrates and phosphatidyl serine, the glucose intake, and subsequently the glucose content in the brain cells, is markedly increased. In the short term, this makes possible an especially marked increase in the cognitive functional capacity. Furthermore, when consumed regularly, three to four bars per week suffice to sustain a long-term increase of cognitive functional capacity. *See* paragraphs [0025] and [0053] of the published application.

Additionally, the invention provides methods for improving cognitive functional capacity in consumers of the claimed food product/bar. *See* paragraphs [0025] and [0053] of the published application and claim 3 as originally filed.

### Argument

To begin, Applicant respectfully submits that the arguments and data presented in the previously-filed Responses and Declarations (filed on June 12, 2009 and December 19, 2008) sufficiently refute the Examiner's case of obviousness. Thus, the current Response both emphasizes previous points that the Examiner has apparently failed to appreciate and addresses additional assertions made by the Examiner in the current Office Action.



Applicant respectfully submits that the combination of Buchholz and Lang does not obviate the invention as currently claimed. Independent claims 14, 23, and 32 recite, *inter alia*, a food/food bar for improving cognitive functional capacity of a consumer of the food/food bar. The food/food bar includes a combination of a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of simple carbohydrates selected from the group consisting of glucose, fructose, sucrose, and combinations thereof. Upon consumption of the food/food bar containing the combination of phosphatidyl serine and simple carbohydrates glucose intake into the brain cells of the consumer is improved. Additionally, independent claim 47 recites, *inter alia*, a method for a consumer to improve cognitive functional capacity by consuming the food/food bar as currently claimed in claims 14, 23, and 32.

The Examiner asserts that although Buchholz does not explicitly teach the role of carbohydrates in improving cognitive function of the brain, Lang remedies this deficiency by disclosing a starch-containing cereal product that improves cognitive performance. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to incorporate carbohydrates into the composition of Buchholz, since Lang teaches that food products containing carbohydrates such as starch improve cognitive performances.

Applicant respectfully disagrees. As noted above, the invention, as currently claimed, is a food/food bar, including a combination of a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of simple carbohydrates selected from the group consisting of glucose, fructose, sucrose, and combinations thereof, for improving cognitive functional capacity. A food/food bar including such a combination of phosphatidyl serine and simple carbohydrates is not suggested by the combined teachings of Buchholz and Lang nor is there any reasonable basis for suggestion or motivation to combine the teachings in the first place.

Buchholz teaches a composition for restoring aberrant transmethylation reactions in the treatment of transmethylation disorders. In this composition phosphatidyl serine acts as a carbon

donor. Lang teaches a breakfast food product including slowly digestible starch. There is little association between a therapeutic composition and a food. Thus, as clear from both the above teachings of Buchholz and Lang and the arguments presented in the previous Responses, the compositions of Buchholz and Lang are unrelated to each other and to the invention.

The Examiner persists in her superficial analysis of Lang by continually repeating the assertion that Lang teaches that food products containing carbohydrates, such as starch, improve cognitive performances. However, the actual teachings of Lang provide a more complex view of the effects of carbohydrates on cognitive function. As established in the previous Response at page 14, Lang does not disclose that foods merely containing “starch” or “carbohydrates” are capable of improving cognitive function, but rather discloses a cereal product, having a specific ratio of slowly-digestible starch to total starch content, which is capable of improving cognitive function. The positive effects on cognitive function are due to the choice of the appropriate ratio and not simply from an inclusion of carbohydrates. This is clearly evident in the experimental examples of Lang wherein he tested his food product against ready-to-eat cereals that also contained carbohydrates, but did not improve cognitive functions.

*A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). See MPEP 2142.02 VI.*

In Example 1, Lang compares the effects of his composition (biscuits) and commercial ready-to-eat cereals on learning in rats. Although no particular brand of ready-to-eat cereal is identified, the high sugar content of cereals, especially those made for children, is very well known. The results of the comparison showed that the consumption of biscuit is followed by learning which is significantly superior to that following the consumption of cereals. See paragraph [0071] and Figures 1 and 2. Furthermore, Lang’s results specifically showed a decrease in attention after consumption of the ready-to-eat cereals. See paragraph [0075].

As described above, the food/food bar, as currently claimed, comprises a combination of phosphatidyl serine and simple carbohydrates which when consumed, improves cognitive functions, such as memory, concentration, learning, and attentiveness. Therefore, when considering Lang as a whole, as is required for proper analysis under 35 U.S.C. §103(a), it is clear that the results of Example 1 contradict the results of the invention, *i.e.* foods containing high amounts of simple sugars decrease cognitive function. Thus, Lang's results negate any apparent reason to combine. Furthermore, considering that Lang discloses a food having an effect opposite the effect of the claimed food/food bar, Lang can be considered as teaching away from the food/food bar as currently claimed.

This is not to say that Lang's experimental results negate his disclosure that carbohydrates improve cognitive function. However, in light of contradictory data (such as Example 1 of Lang regarding the effects of carbohydrate on cognitive functions), this teaching alone is not sufficient to suggest combination with the teachings of Buchholz. Such contradictory data sheds doubt on the predictability of the combination of Buchholz and Lang.

Even in the rare instance that one would combine the disclosures of Buchholz and Lang, in light of all the above, why would one of ordinary skill in the art be motivated to incorporate any part of Lang's composition into Buchholz's composition? Why would want Buchholz want to use carbohydrates (as disclosed in Lang) to improve cognitive function when his composition is already disclosed as useful for improving cognitive function? No reason for such combination is suggested in the art. Why would one want to combine the teachings of Buchholz and Lang when Lang teaches simple carbohydrates have a negative effect on cognitive performances? Further, where is the suggestion that the addition of a specific ratio of slowly-digestible starch to total starch or addition of simple carbohydrates to the food product of Buchholz improves or enhances Buchholz's food product? At the time of the invention, would one think that slowly-digestible starches or simple carbohydrates can improve or enhance the function of phosphatidyl serine? Without answers to these questions, one of ordinary skill in the art would have no reason or motivation to combine the teachings of Buchholz and Lang.

### Declaration

The following arguments are in response to the Examiner's position, set forth in item 7 of the current final Office Action, regarding the Declaration (filed on June 12, 2009).

The Examiner asserts that the Declaration under 37 C.F.R. 1.132, filed on June 12, 2009, is insufficient to overcome the rejection of the claims.

Applicant strongly disagrees with the Examiner's assertion.

First, Applicant points out that the currently claimed food/food bar includes a combination of a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of simple carbohydrates selected from the group consisting of glucose, fructose, sucrose, and combinations thereof.

The claimed food/food bar provides measurable improvements in cognitive functional capacity upon consumption that can not be predicted from the teachings of Buchholz and Lang. The effect of the combination of phosphatidyl serine and carbohydrates on concentration, memory, and attention is demonstrated in the first experimental example provided in both of the previously-submitted Declarations (December 19, 2008 and June 12, 2009) of the inventor, Dr. Kurt-Reiner Geiss. In this experiment, improvements in concentration, memory, and attention were observed in the subjects after twelve weeks of consuming the bars and the improvements declined after the subjects stopped consuming the bars.

The study volunteers were evaluated pre-supplementation and after twelve weeks of consuming one IQPLUS Brain Bar per day for the first two weeks, followed by half an IQPLUS Brain Bar for the next ten weeks. The IQPLUS Brain Bar contains 200mg of phosphatidyl serine and 20g of simple carbohydrates. After the second evaluation, the volunteers stopped consuming the IQPLUS Brain Bars and were re-evaluated during week twenty-four. The combination of phosphatidyl serine and simple carbohydrates in the form of the IQPLUS Brain Bar resulted in improvements in all categories of concentration, attention, and memory tested (results after

twelve weeks of IQPLUS Brain Bar consumption in comparison to starting values). A comparison of results after twelve weeks consumption with results after an additional twelve weeks without any further supplementation showed a decline in all categories at week twenty-four. The results regarding concentration and attention are shown in Table 2 and results regarding memory and attention are shown in Table 3 (Declaration filed December 19, 2008, experimental example one).

With regard to this experiment, the Examiner suggests that the data presented is not commensurate in scope with the claims and states *“The declaration provides data for only 200mg of phosphatidyl serine and 20g of carbohydrates whereas the claims as recited have the limitation of a minimum of 100mg of phosphatidyl serine and a minimum of 10g carbohydrates, as such no data has been provided for amounts which are below 200mg of phosphatidyl serine and less than 20g of carbohydrates.”*

Applicant disagrees and respectfully points out that the exact assertion was already presented in the previous Office Action and subsequently addressed in the previous Response. However, this assertion is again addressed herein for the convenience of the Examiner.

The claims, as currently pending, recite minimums of about 100mg to 200mg phosphatidyl serine and about 10g to 20g simple carbohydrates. The subjects participating in the IQPLUS Brain Bar study (experimental example 1, described above) consumed one bar, one bar including 200mg phosphatidyl serine and 20g of simple carbohydrates, per day for the first two weeks of the study. The subjects then consumed a half of a bar for the following twelve weeks. One half of a bar contains 100mg of phosphatidyl serine and 10g of simple carbohydrates. Accordingly, the average consumption per subject was 117mg of phosphatidyl serine and 11.7g of simple carbohydrates for the duration of the twelve week study. Thus, the range of amounts of phosphatidyl serine and simple carbohydrates exemplified in the experimental examples is commensurate with the range of amounts claimed.

Although the claimed range of amounts of phosphatidyl serine and simple carbohydrates is adequately represented by the data, Applicant notes that results over the entire range of properties is not required to establish a sufficient rebuttal of obviousness.

*When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. Id. See MPEP 2145.*

Furthermore, Applicant is confused by the Examiner's requirement for a showing of data over the entire range of claimed amounts of phosphatidyl serine and carbohydrates, since her position is that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations. See page 6 of the current final Office Action. Thus, considering her position, data regarding such ranges is not "inventive" and therefore, should be irrelevant in a determination of obviousness. However, the Examiner appears to improperly require such data to convince her that the Declaration is sufficient for overcoming the rejection.

The Examiner refers to the previous Response and states "*Applicants themselves state on page 15 of the response that certain phosphatidyl serine did not show any cognitive performance and thus there exists unpredictability in cognitive improvement. If such is the case, (which applicants assert with regard to Buchholz and Lang), then applicants own invention is unpredictable because claim 1 does not recite any specific source of phosphatidyl serine or any specific carbohydrates.*"

This paragraph referred to by the Examiner (at page 15 of the previous Response) states "*Additionally, at the time of the invention, less than definitive data on the influence of phosphatidyl serine on cognitive function and memory was also present in the prior art. For example, results from an experiment disclosed by Jorissen et al. (Nutrition Neuroscience*

*4(2):121-134 2001; abstract attached hereto as “Exhibit A”) concludes that a daily supplement of phosphatidyl serine (300mg or 600mg for 12 weeks) does not affect memory or other cognitive functions in older individuals with memory complaints. Conversely, Schreiber et al. (Israeli Journal of Psychiatry and Related Science 37(4):302-307 2000; abstract attached hereto as “Exhibit B”) demonstrates improvement in patients having age-related cognitive decline after supplementation with 300mg phosphatidylserine for twelve weeks.”*

In light of her statement, Applicant respectfully submits that the Examiner fails to recognize the purpose of the Exhibits.

When an Examiner presents a *prima facie* case of obviousness, Applicant can submit evidence to show that the claimed subject matter would have been non-obvious. *See* MPEP 2141 IV. In the instant application, the food/food bar, as currently claimed, improves cognitive functional capacity of a consumer (of the food/food bar). The improvement is a result of a combination of phosphatidyl serine and simple carbohydrates included within the composition of the food/food bar. The Examiner asserts that this combination is obvious and predictable from the disclosures of Buchholz and Lang.

Applicant submits that, at the time of the invention, available data was less than definitive regarding the influence of phosphatidyl serine or simple carbohydrates (discussed above regarding experimental results of Lang) on cognitive function. Exhibits A and B were not intended for direct comparison with the claimed invention, but rather were provided as evidence to support Applicant’s assertion regarding the state of the prior art at the time of the invention; for example Jorissen (Exhibit A) demonstrates no effect on cognitive function and Schreiber (Exhibit B) demonstrates an improvement. Thus, one of ordinary skill in the art would not necessarily consider the effect of phosphatidyl serine on cognitive function to be predictable. The noted presence of conflicting data sheds doubt on the alleged predictability of the claimed invention. Without a reasonable measure of predictability, there is no suggestion/motivation to combine the teachings of Buchholz and Lang or any other prior art, *i.e.* Exhibits A and B negate an apparent reason to combine.

By asserting that Applicants own invention is unpredictable, the Examiner contradicts her own argument. If the invention is predictable in light of Buchholz and Lang, how can it now be “unpredictable”?

The invention can not be both predictable in light of Buchholz and Lang and unpredictable in light of other prior art.

The Examiner appears to require a recitation of a specific source of phosphatidyl serine and specific carbohydrates. Claim 32 recites lecithin as a source of phosphatidyl serine. Claims 14, 23, and 32 recite specific simple carbohydrates, glucose, fructose, and sucrose. Additionally, several sources of and methods for producing phosphatidyl serine are disclosed at paragraphs [0035]-[0038] of the published application. The use of simple carbohydrates, *i.e.* a specific category of carbohydrates, is disclosed in both of the previously-filed Declarations and at paragraphs [0020] and [0052] of the published application. Regardless, Applicant respectfully submits that no such recitation (source of phosphatidyl serine and specific carbohydrates) is required to show the unexpected improvement of cognitive function provided by the claimed food/food bar.

The Examiner asserts that “*By definition, synergistic affect means that there is some affect associated with the compound by itself.*”

Applicant respectfully submits that the Examiner’s definition is incorrect. The whole idea of synergism is compounds together, not a compound “by itself”. Synergism is the interaction of elements that when combined produce a total effect that is greater than the sum of the individual elements. *See* Exhibit D as attached to the previous Response and MPEP 716.02(a) I.

The Examiner does not find any synergism in Applicant’s examples and asserts that a review of Figure 3 does not show any difference between pre and post carbohydrate levels.

Again Applicant respectfully points out that the exact assertion was already presented in the previous Office Action and subsequently addressed in the previous Response. However, the assertion is again addressed herein for the convenience of the Examiner.



The data clearly reflects a measurable difference in performance between pre and post carbohydrate levels. The Carbohydrate group showed an improvement of 1.3% (post 7.9, pre 7.8; difference  $0.1=1.3\%$  improvement) in comparison to an improvement of 21.7% for the PS and Carbohydrate Group (post 10.1, pre 8.3; difference  $1.8=21.7\%$  improvement). *See* section entitled “result” at the bottom of page 6 of the Declaration filed on December 19, 2008). Thus, in contrast to the Examiner’s assertion, the data shows a difference in performance between pre and post carbohydrate levels.

The synergistic effect is apparent from even a quick comparison of the dark bars (post supplementation) of Figure 3 (at page 7 of the Declaration filed on December 19, 2008) showing that the golfers who consumed the food bar (phosphatidyl serine and a mixture of glucose, sucrose, and/or fructose, *i.e.* simple carbohydrates) achieved a greater amount of correct ball flights than did the golfers who consumed carbohydrates alone or phosphatidyl serine alone combined. This combination of phosphatidyl serine and simple carbohydrates resulted in a statistically significant ( $p < 0.05$ ) improvement of good ball flights, which can result with improved golf scores overall. *See* section entitled “Results” at pages 6-7 of the Declaration filed on June 12, 2009). Furthermore, regarding the data of Figure 3, if one achieves only a small increase with phosphatidyl serine or carbohydrates, one would not expect the combination to provide greater and/or better results.

Additionally, Applicant conducted a further experiment with golfers using identical conditions as the above-described experiment (Experimental Example Two). The subjects ( $n=2$ ) consumed 150mg of phosphatidyl serine and 15g of carbohydrates on average per day for a period of eight weeks. This group showed a 14% improvement in good ball flights (pre 6.5; post 7.4; difference  $0.9 = 14\%$ ). *See* “Experimental Example Three” of the Declaration filed on June 12, 2009.

The Examiner asserts that the claims do not recite the synergistic effect of phosphatidyl serine and carbohydrates and concludes that the scope of the claims is not commensurate with the Declaration.

In response, Applicants point out that the claimed effect, *i.e.* improved cognitive functional capacity, is a result of the synergistic effect of phosphatidyl serine and simple carbohydrates. Thus, contrary to the Examiner's assertion, the Declaration and the claims are commensurate in scope.

The Examiner continues to draw incorrect conclusions from the graph at page 6 (Figure 3) of the Declaration filed on June 12, 2009. *"Applicant declares on page 6 under result section, that there was no difference in cognitive performance in pre and post tests with PS or carbohydrate once consumed individually. This comparison is not direct comparison with the prior art's teaching which teaches that PS increases cognitive performance as disclosed by Buchholz and carbohydrates increase cognitive performance as disclosed by Lang et al."*

The comparison is between the effect of phosphatidyl serine and carbohydrates consumed individually as disclosed by the prior art (Buchholz and Lang) and the effect of phosphatidyl serine and carbohydrates consumed individually as demonstrated by the data in the Declaration. Therefore, contrary to the Examiner's conclusion, it can be considered a direct comparison of individual effects. Regardless, Applicant respectfully submits that this conclusion has no relevance. A direct comparison is not required in order to show an unexpected synergistic effect.

Three groups of data evaluating golf ball flights are shown in Figure 3; one group for subjects consuming phosphatidyl serine alone; a second group for subjects consuming carbohydrates alone; and a third group for subjects consuming the combination of phosphatidyl serine and simple carbohydrates. At the start, ball flights were measured in order to establish a baseline performance (pre-test). The baseline performance is used for comparison against performance measured after a time period of consuming the assigned food such that any improvements can be determined. Thus, the baseline performance functions as a "control" for the experiment. The effects of carbohydrates and phosphatidyl serine were measured individually in order to show that the significant improvement in performance is due to the combination and not to either the carbohydrate or the phosphatidyl serine alone. Since carbohydrate alone and phosphatidyl serine alone did not improve performance, one would not

expect to obtain improved performance from the combination. However, the data clearly shows a statistically significant improvement resulting from consumption of the combination of phosphatidyl serine and simple carbohydrates. This is evidence of an unexpected synergistic effect which negates any reason to combine the teachings of the references.

Regarding the test subjects, the Examiner states “*Results from only 2 subjects consuming PS do not provide any statistical significance. The rationale behind having 10 subjects consuming carbohydrate and only 2 subjects consuming PS is not clear to the Examiner.*”

The rationale for having only two subjects in the phosphatidyl serine group, ten subjects in the carbohydrate group, and ten subjects in the combination (phosphatidyl serine and carbohydrates) group is scientific as well as financial. The phosphatidyl serine group consumed 200mg of phosphatidyl serine. Based upon existing literature, this low amount of phosphatidyl serine was not expected to have any effect on the study parameters. In order to reduce costs for the total study, a smaller sample size in the phosphatidyl serine group was tested as no effect was expected. If even a small effect was found, the sample size for the phosphatidyl serine group would have been increased, but there was no scientific reasoning or effect to justify the additional expenses.

The Examiner further states “*Instant claims recite the minimum effective amount for improving cognitive performance to be 100mg, the declaration on page 6, recognizes that there is no difference in results pre and post test, it is unclear to the Examiner how a nutritional bar with a 100mg PS will improve cognitive performance when the one with 200mg, does not show any difference in cognitive performance compared to one without any PS.*”

Applicant respectfully submits that the Examiner appears to lack understanding of both the claimed invention and the data presented in the previously-filed Declarations. The food/food bar, as currently claimed, comprises a combination of phosphatidyl serine and simple carbohydrates. The claims do not recite that a 100mg or any amount of phosphatidyl serine alone is effective for improving cognitive function. The results showing no difference in performance pre and post test reflect consumption of phosphatidyl serine alone. The

improvement obtained from the food/food bar containing 100mg phosphatidyl serine is due to the combination of phosphatidyl serine and simple carbohydrates. No comparison is made between a food/food bar containing 100mg phosphatidyl serine alone and a food/food bar containing 200mg phosphatidyl serine alone.

Accordingly, based upon data presented in both previously-filed Declarations, in contrast to the Examiner's conclusions, it is clear that Applicant has provided evidence of a synergistic effect on cognitive functional capacity from the combination of phosphatidyl serine and simple carbohydrates over the effect of each ingredient alone (*i.e.* phosphatidyl serine alone and simple carbohydrates alone).

Furthermore, as established above, one of ordinary skill in the art would not consider the compositions of Buchholz and Lang as analogous or related in any way. One would not have any reason or motivation for incorporating the carbohydrates of Lang into the composition of Buchholz because neither Lang nor other prior art suggests that specific ratios of slowly-digestible starch to total starch or simple sugars combined with phosphatidyl serine would improve/increase the ability of Buchholz's composition to treat transmethylation disorders. Regardless, the incorporation would not result with the food/food bar as currently claimed.

Neither the cited patent documents (Buchholz and Lang) nor any other prior art teach or suggest a food/food bar (or methods for using the food/food bar), including a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of simple carbohydrates selected from the group consisting of glucose, fructose, sucrose, and combinations thereof, for improving the cognitive functional capacity of a consumer of the food/food bar. Thus, even if one of ordinary skill in the art were to combine the teachings of Buchholz and Lang, the food/food bar, as currently claimed, would not be the result. Additionally, neither the cited patent documents nor other prior art teach the unexpected beneficial results (synergistic effect) of the combination of at least a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of simple carbohydrates, particularly simple carbohydrates having a high glycemic index.

Accordingly, Applicant respectfully submits that independent claims 14, 23, 32, and 47 are patentable over Buchholz in view of Lang. As claims 15, 18, 19, and 37 depend from claim 14; claims 24-31, 36, and 38 depend from claim 23; claims 33, 35, and 39 depend from claim 32; and claims 48 and 49 depend from claim 47, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that the dependent claims are allowable over Buchholz in view of Lang at least for the same reasons.

In light of the foregoing arguments, previously-filed arguments, and both the previously-filed Declarations under 37 C.F.R. § 1.132 (including the Exhibits), Applicant requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

### **Conclusion**

In light of the foregoing amendments, remarks, and both of the previously-filed Declarations under 37 C.F.R. § 1.132 (including the Exhibits) this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned. No fees are believed to be due at this time. However, please charge any required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-018).

Respectfully submitted,

/Paul D. Bianco/

Paul D. Bianco, Reg. # 43,500

Customer Number: 27317  
FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.  
21355 East Dixie Highway, Suite 115  
Miami, Florida 33180  
Tel: 305-830-2600; Fax: 305-830-2605  
e-mail: pbianco@fggbb.com